FORM PTO-1390 (Rev 5-93) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5)
NITROS P158US	10/089652

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/IB00/01400	October 2, 2000	October 1, 1999

TITLE OF INVENTION

LITHOTRIPTER APPARATUS

APPLICANT(S) FOR DO/EO/US

Patrick SANGOUARD

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ■ This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
3. ■ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ■ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ■ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ■ has been transmitted by the International Bureau. (PCT/IB/308 mailed **12 April 2001**).
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ■ A translation of the International Application into English (35 U.S.C. 371(c)(2)) is attached.
7. ■ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ■ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ■ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). (unsigned)
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98 with PTO FORM 1449.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ■ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification w/Marked-Up Version of Amended Specification.
15. ☐ A change of power of attorney and/or address letter.
16. ■ Other items or information:
    - ■ Preliminary Examination Report
    - ■ Annexes to Pre. Ex. Rep.
    - ☐ International Search Report
    - ☐ German Novelty Search Report
    - ☐ ___ copies of citations
    - ■ Form PCT/IB/308
    - ■ International Publ. No. **WO 01/24712 A1** (Face page only)
    - ■ Copy of Request
    - ■ Submission of Formal Drawings
    - ■ 4 sheets of formal drawings
    - ■ Abstract
    - ☐ **Applicant Claims Small Entity Status**
    - ☐ Copy of Notification of File Missing Parts
    - ■ French Language Specification

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this Transmittal Letter and the papers indicated as being transmitted therewith is being deposited with the United States Postal Service on this date **April 1, 2002** in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number **EL 918840107 US** addressed to the: Box PCT, Assistant Commissioner of Patents, Washington, D.C. 20231.

Michael J. Bujold
(typed or printed name of person mailing paper)

Michael J. Bujold
(signature of person mailing paper)

PATENT & TRADEMARK OFFICE

020210

17. ■ The following fees are submitted:	CALCULATIONS	PTO USE ONLY
Basic National Fee (37 CFR 1.492(a)(5):		
Search Report has been prepared by the EPO or JPO $890.00		
International preliminary examination fee paid to USPTO (37 CFR 1.492)(a)(1) .. $710.00		
No international preliminary examination fee paid to USPTO (37 CFR 1.492)(a)(2) but international search fee paid to USPTO (37 CFR 1.445(a)(2)). $740.00		
Neither international preliminary examination fee (37 CFR 1.492)(a)(3) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO $1040.00		
International preliminary examination fee paid to USPTO (37 CFR 1.492)(a)(4) and all claims satisfied provisions of PCT Article 33(1)-(4) $100.00		
ENTER APPROPRIATE BASIC FEE AMOUNT =	890	
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	0	

Claims	Number Filed	Number Extra	Rate		
Total Claims	8 - 20 =	0	x $18.00	0	
Independent Claims	1 - 3 =	0	x $84.00	0	
Multiple dependent claim(s) (if applicable)			+ $280.00	0	
			TOTAL OF ABOVE CALCULATIONS =	890	
Reduction by ½ for filing by small entity, if applicable. **Applicant Claims Small Entity Status.** (Note 37 CFR 1.9, 1.27, 1.28).				0	
			SUBTOTAL =	890	
Processing fee of $130.00 for furnishing the English translation later the ☐ 20 ☐30 months from the earliest claimed priority date (37 CFR 1.492(f)).			+	0	
			TOTAL NATIONAL FEE =	0	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property			+	0	
			TOTAL FEES ENCLOSED =	890	
			Amount to be: refunded		$
			charged		$

a. ■ A check in the amount of $ **890.00** to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. 04-0213 in the amount of $____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ■ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 04-0213 . A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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PATENT & TRADEMARK OFFICE

020210

04/1/02

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Patrick SANGOUARD
Serial no.	:	
For	:	LITHOTRIPTER APPARATUS
Docket	:	NITROS P158US

BOX PCT
The Commissioner of Patents and Trademarks
Washington, D.C. 20231

FIRST PRELIMINARY AMENDMENT

Dear Sir:

By way of preliminary amendment, please amend the above identified application as set forth below.

In the Specification:

Please cancel paragraphs 2, 4, 11, 20 and 26 of the specification, in their entirety, in favor of a clean form of paragraphs 2, 4, 11, 20 and 26 of the specification, without any markings thereon, as follows. Accompanying this response is a copy of the original paragraphs of the specification which show the additions (by underlining and bold) and the deletions (by strikeout) to the canceled specification paragraphs. Please enter the replacement specification paragraphs into the record of this case.

In the Claims:

Please cancel claims 1-8, without prejudice or disclaimer of the subject matter therein, in favor of new claims 9-16 as follows.

[002] FIELD OF THE INVENTION

[004] BACKGROUND OF THE INVENTION

[011] SUMMARY OF THE INVENTION

[020] BRIEF DESCRIPTION OF THE DRAWINGS

[026] DETAILED DESCRIPTION OF THE INVENTION

9. (NEW) A lithotripter apparatus comprising a frame (11), a treatment table (12) for supporting a patient during the process of fragmenting a lithiasis (35), a device for generating shock waves by means of an electrical arc, a means for focusing these shock waves on said lithiasis, and a device (60) for live viewing of the treatment zone, said device for generating shock waves comprising a first electrode (33) and a second electrode (34) separated from each other and connected to a high voltage energy generating circuit, and the means for focusing these shock waves comprising a semi-ellipsoidal reflector (17), an extremity (33a) of the first electrode (33) and an extremity (34a) of the second electrode (34) being located essentially at a first focal point (F_e) of the reflector (17), a second focal point (F_r) of the reflector being centered on said lithiasis, said electrodes being equipped with a means of wear compensation, characterized in that said means for wear compensation on the electrodes (33, 34) comprises at least one compensation mechanism which axially displaces the first and second electrodes, independently of each other, along an axis corresponding to an axis of symmetry of the reflector (17) and turns at least one of said electrodes on its longitudinal axis.

10. (NEW) The apparatus according to claim 9, wherein the first electrode is located along the axis of the reflector (17) and housed inside a tube (41) which is joined to a first mechanism designed to axially displace said tube along with the first electrode it contains and to cause said tube to rotate along its longitudinal axis.

11. (NEW) The apparatus according to claim 9, wherein the second electrode (34) comprises a first and second portion (44, 45) connected to each other by a small bar (46), a first portion being located along the axis of the reflector (17) and the second portion (45) being housed inside a tube (47) which is connected to a second mechanism designed to axially displace said tube along with the electrode it contains.

12. (NEW) The apparatus according to claim 9, further comprising a computer designed to determine the spatial coordinates of the lithiasis to be treated (35) and of the reflector (17), a means for emitting control signals as a function of the values determined for said spatial coordinates, and a means for displacing said reflector as a function of said signals so as to position the receptor focal point (F_r) on said lithiasis.

13. (NEW) The apparatus according to claim 12, wherein the means for displacing the reflector (17) comprises a housing (40) that holds a basin constituting the

reflector, a chariot to which the housing is attached, a plurality of essentially horizontal slides that are crossed allowing the chariot to be displaced in two orthogonal directions, a plurality of essentially vertical slides allowing it to be displaced in a third direction perpendicular to the two other directions, as well as one or more devices activating the chariot in these three directions.

14. (NEW) The apparatus according to claim 9, wherein the device for live viewing of the treatment zone includes a radioscopic apparatus comprising an x-ray generator (62) and an x-ray receiver (63), respectively attached to a first and second extremity of an arc-shaped arm (61) pivoting in its plane about its center, a scree (18) for displaying the radioscopic images, and a means for communicating the visual data to a computer in order to determine the relative coordinates of the emitting first focal point (F_e) and of the lithiasis.

15. (NEW) The apparatus according to claim 9, wherein the live viewing device (60) comprises an echograph device as well as a plurality of cameras which are offset from each other, a screen for displaying the echograph images and a means for communicating the visual data to said computer in order to determine the relative coordinates of the emitting first focal point (F_e) and of the lithiasis.

16. (NEW) The apparatus according to claim 15, wherein a first camera is located at the base of the apparatus, below the treatment zone, in order to furnish an image essentially perpendicular to said zone, and a second camera is offset to the side in order to furnish an image oblique to said zone.

REMARKS

Accompanying this response, please find marked-up paragraphs of the specification which overcome some informalities noted in the specification. The undersigned avers that the enclosed replacement paragraphs of the specification do not contain any new matter.

Please consider new claims 9-16 upon consideration of this application.

In the event that there are any fee deficiencies or additional fees are payable, please charge the same or credit any overpayment to our Deposit Account (Account No. 04-0213).

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

[001] LITHOTRIPTER APPARATUS

[002] ~~TECHNICAL DOMAIN~~**FIELD OF THE INVENTION**

[003] The present invention concerns a lithotripter apparatus comprising a frame, a treatment table for supporting the patient during the procedure of fragmenting, a lithiasis, a device for generating shock waves using an electrical arc, a means for focusing said shock waves onto said lithiasis, and a device for viewing the procedure live, said shock wave generating device comprising two electrodes that are separated from each other and connected to a high voltage energy generator and the means for focusing said shock waves comprising a semi-ellipsoidal reflector, with the ends of said electrodes being located generally at one of the focal points of the reflector and the other focal point of said reflector being centered on said lithiasis, said electrodes being equipped with a means that compensates for wear.

[004] ~~PRIOR ART~~ **BACKGROUND OF THE INVENTION**

[005] A lithotripter is an apparatus designed to break up calcium kidney stones or lithiases, for example, using shock waves generated by an electric arc focused on points within the deposits inside the kidneys. The shock waves are generated by electrical arcs that are produced at one of the focal points, called the emission focal point, of a semi-ellipsoidal metal reflector which forms a basin. The basin is filled with salt water during the procedure and it is covered with a flexible, watertight membrane that is applied directly to the patient's skin to ensure a continuously conductive environment for the shock waves. The reflector is positioned so that the other focal point, called the receptor focal point, is located inside the lithiasis to be broken up or destroyed.

[006] The effectiveness of such a device and the reliability of the treatment depend primarily upon precisely positioning the receptor focal point on its target. To achieve this, two control means are necessary. One concerns the precise positioning of the electrodes which generate the electric arc relative to the emission focal point, and the other concerns the precise positioning of the receptor focal point relative to the lithiasis, which should be viewed live to allow precise positioning.

[011] ~~EXPLANATION~~**SUMMARY** OF THE INVENTION-

[012] The apparatus of the invention overcomes these various difficulties and provides an effective method of breaking up lithiases by applying shock waves which are perfectly adapted in strength and precisely aimed, thereby eliminating the possibility of causing lesions in surrounding tissue. This is due specifically to the fact that the system for compensating wear on the electrodes proposed by the invention eliminates diagonal wear on the electrodes that causes the shock wave generator to become off-center relative to the emission focal point on the reflector. Furthermore, this device is easily manageable in comparison with known devices, making the procedure simple, quick, and efficient, since its aim is very precise. Moreover, the auxiliary equipment such as the viewing devices are not dedicated devices, and they can be used for other purposes.

[013] This goal is achieved by the lithotripter apparatus of the invention, characterized in that said means for compensating wear on the electrodes comprises at least one compensation mechanism for axially displacing the two electrodes independently of each other along an axis corresponding to the axis of symmetry of the reflector and to cause at least one of said electrodes to turn on its longitudinal axis. Because of this, the extremities of the electrodes wear regularly and can always be positioned precisely so that the shock wave generator which they constitute is centered on the emission focal point of the reflector forming the basin, whatever the extent of wear on the electrodes. As a result of this, one of the basic conditions set forth above, i.e., that the shock waves be properly aimed at the lithiases to be treated, is fulfilled.

[014] In a particularly advantageous manner, one of the electrodes is located along the axis of the reflector and housed inside a tube that is joined to a first mechanism which axially displaces the tube and the electrode it holds and rotates the tube on its longitudinal axis. The other electrode comprises two portions connected to each other with a small bar, one of said portions being located along the axis of the reflector and the other portion being housed inside a tube that is connected to a second mechanism which axially displaces the tube along with the electrode it holds.

[020] ~~SUMMARY~~**BRIEF** DESCRIPTION OF THE DRAWINGS

[021] The present invention will be better understood with reference to the following description of a preferred embodiment of the lithotripter apparatus according to the invention and with reference to the drawings, provided by way of non-limiting examples, in which:

[022] Figure 1 shows a perspective view of the entire apparatus of the invention;

[023] Figure 2 is a schematic view showing the operating principles of the apparatus of the invention;

[024] Figure 3 is a schematic axial cross-section of the reflector and the electrodes of the lithotripter apparatus of the invention; and

[025] Figure 4 is a particular embodiment of the viewing device associated with the apparatus of the invention.

[026] ~~METHOD(S)~~**DETAILED DESCRIPTION** OF ~~ACHIEVING~~ THE INVENTION

[027] With reference to Figure 1, the lithotripter apparatus 10 as shown essentially comprises a frame 11 surmounted by a treatment table 12 which supports the patient to be treated. Frame 11 is in the form of a cabinet, with the right side 13 essentially containing the electrical and electronic equipment, the left side 14 essentially containing the mechanical equipment, and the center portion 15 principally containing a movable chariot 16 which holds a semi-ellipsoidal reflector 17 and a device which generates shock waves for dislocating the lithiases. A screen 18 held by an adjustable support 19 is attached to frame 11. A device for viewing of the treatment zone, one embodiment of which will be described with reference to Figure 4, is preferably independently associated with the device and with screen 18.

[028] Figure 2 is a schematic representation of reflector 17 surmounted by a membrane 31 and containing an acoustic transmitting liquid 32 which provides a continuous transmitting environment for the shock waves when the membrane is applied to the patient's body. The basin-shaped semi-ellipsoidal reflector 17 contains two electrodes 33 and 34, whose extremities 33a and 34a, located opposite each other, are positioned essentially axially relative to emission focal

03/29/02

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Patrick SANGOUARD
Serial no.	:	
For	:	LITHOTRIPTER APPARATUS
Docket	:	NITROS P158US

BOX PCT
The Commissioner of Patents and Trademarks
Washington, D.C. 20231

SUBMISSION OF FORMAL DRAWINGS

Enclosed please find four (4) sheets of formal drawings which are to be entered in this case.

In the event that there are any fee deficiencies or additional fees are payable, please charge the same or credit any overpayment to our Deposit Account (Account No. 04-0213).

Respectfully submitted,

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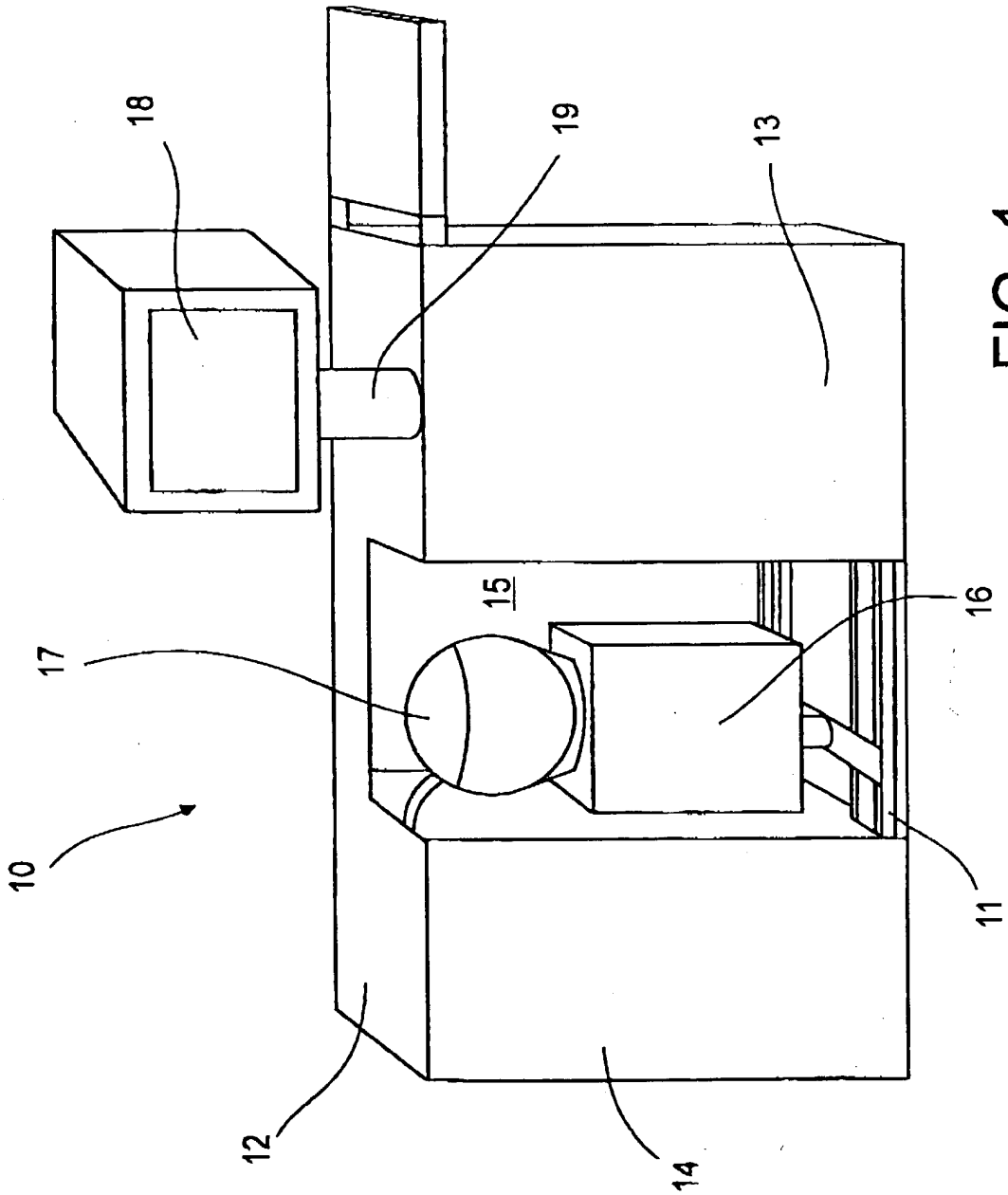

FIG. 1

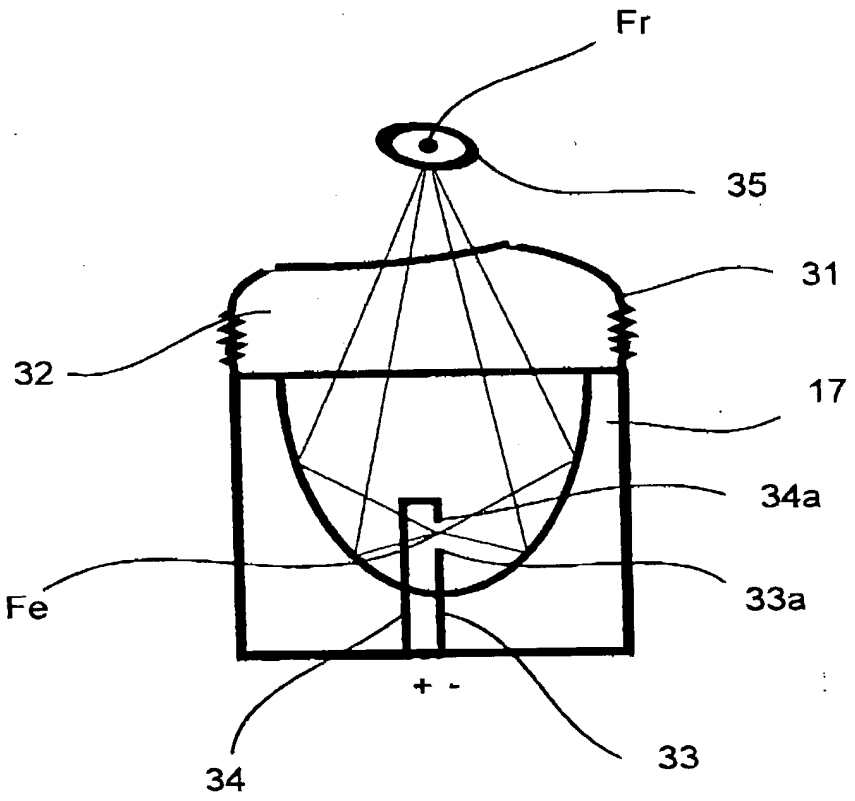

FIG. 2

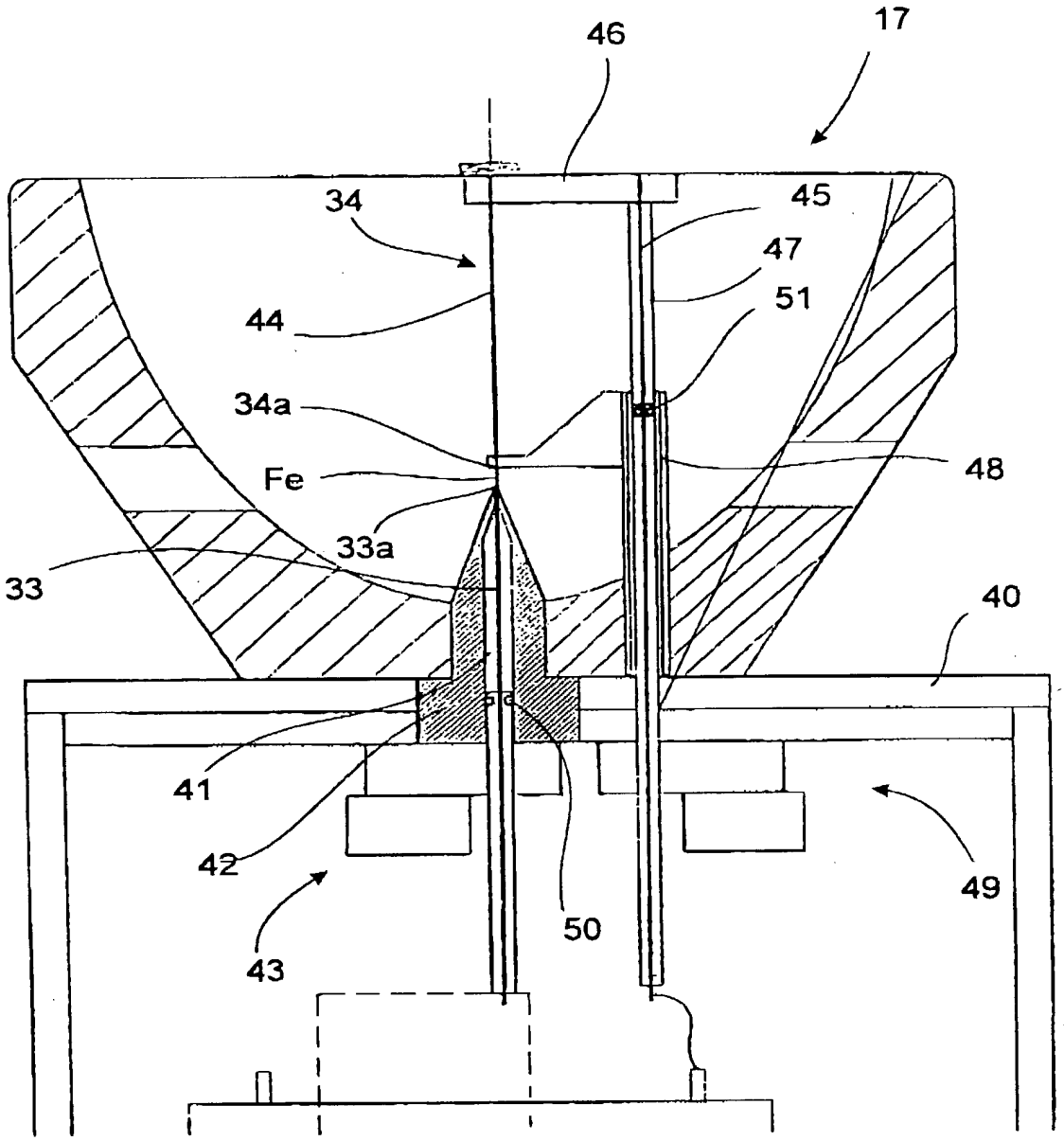

FIG. 3

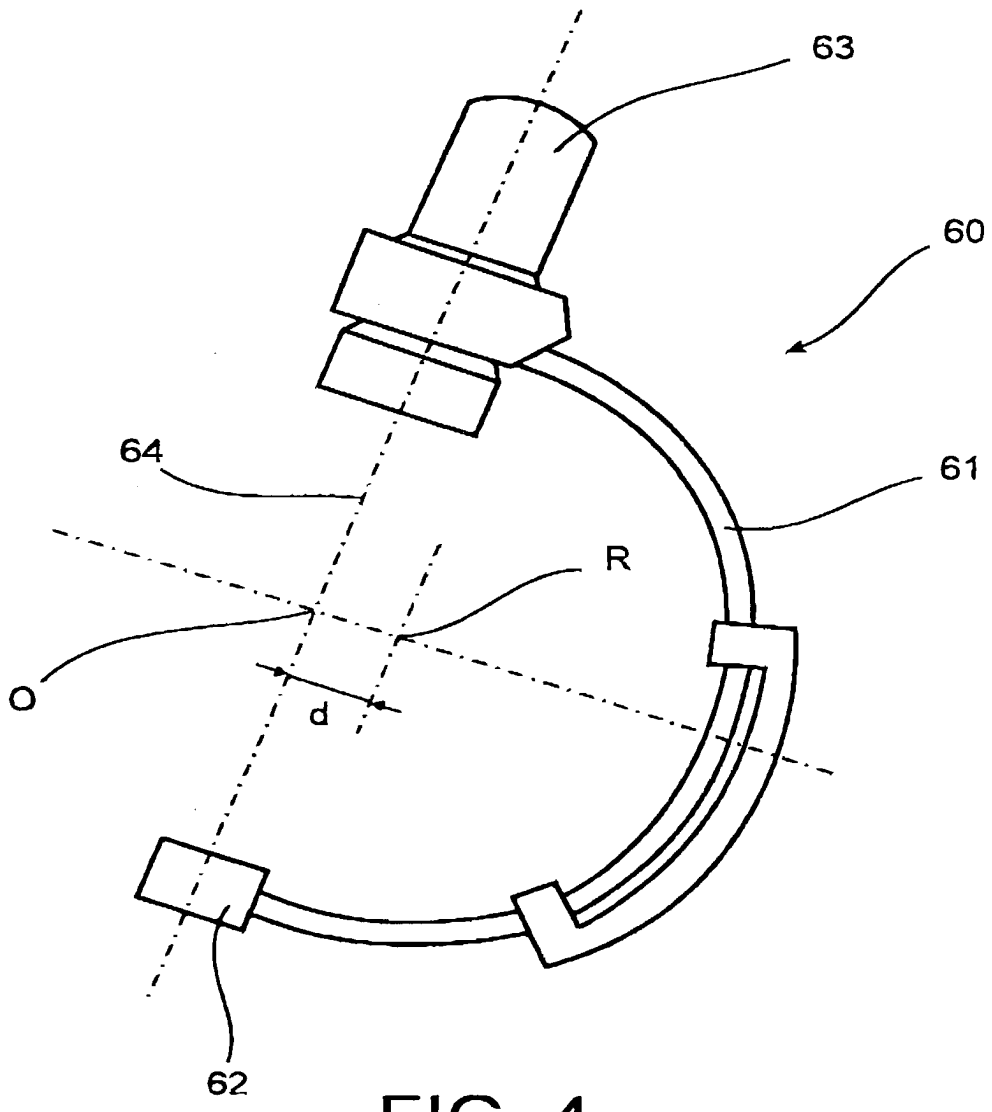

FIG. 4

[001] LITHOTRIPTER APPARATUS

[002] TECHNICAL DOMAIN

[003] The present invention concerns a lithotripter apparatus comprising a frame, a treatment table for supporting the patient during the procedure of fragmenting, a lithiasis, a device for generating shock waves using an electrical arc, a means for focusing said shock waves onto said lithiasis, and a device for viewing the procedure live, said shock wave generating device comprising two electrodes that are separated from each other and connected to a high voltage energy generator and the means for focusing said shock waves comprising a semi-ellipsoidal reflector, with the ends of said electrodes being located generally at one of the focal points of the reflector and the other focal point of said reflector being centered on said lithiasis, said electrodes being equipped with a means that compensates for wear.

[004] PRIOR ART

[005] A lithotripter is an apparatus designed to break up calcium kidney stones or lithiases, for example, using shock waves generated by an electric arc focused on points within the deposits inside the kidneys. The shock waves are generated by electrical arcs that are produced at one of the focal points, called the emission focal point, of a semi-ellipsoidal metal reflector which forms a basin. The basin is filled with salt water during the procedure and it is covered with a flexible, watertight membrane that is applied directly to the patient's skin to ensure a continuously conductive environment for the shock waves. The reflector is positioned so that the other focal point, called the receptor focal point, is located inside the lithiasis to be broken up or destroyed.

[006] The effectiveness of such a device and the reliability of the treatment depend primarily upon precisely positioning the receptor focal point on its target. To achieve this, two control means are necessary. One concerns the precise positioning of the electrodes which generate the electric arc relative to the emission focal point, and the other concerns the precise positioning of the receptor focal point relative to the lithiasis, which should be viewed live to allow precise positioning.

[007] Various devices for performing this treatment are known in the art. However, they all have shortcomings and disadvantages: either they are complicated and costly to manufacture or inaccurate in use, resulting in unreliable, ineffective treatment of patients. One of these problems originates from the imprecise positioning of the shock wave generator, which is ideally placed at the emission focal point on the basin, primarily due to wear on the electrodes that comprise the generator. The distance between the opposite electrode extremities and this focal point causes the aim to be inaccurate, which is the basis for the deficiencies sometimes observed. Another fault is lack of precision in locating the lithiasis. It is essential to determine the position of the lithiasis precisely so the medical personnel can make the receptor focal point of the reflector coincide with the lithiasis, ensuring that the apparatus will perform properly.

[008] In particular, publication FR 2 592 383 has as its objective a frequency shock wave generator for destroying targets such as kidney deposits. This device comprises two electrodes that move in axial translation and which are placed transversely in relation to the reflector's axis of revolution. Because of this design, on the one hand, the arrangement of the electrodes hides a portion of the shock wave generator field; on the other hand, the fact that the electrodes are displaced only axially causes uneven wear on the electrodes and thus has an adverse effect on the precise positioning of the emission focal point.

[009] The latter disadvantage is also a problem in U.S. Patent No. 4,608,983, describing a similar instance with the electrodes moving only in axial translation.

[010] Certain other known devices have a means for moving the patient relative to the apparatus in order to move the lithiasis and the receptor focal point into coincidence or to move the receptor focal point, mechanically connected to the apparatus, into coincidence with the lithiasis. In both cases, the design is heavy and cumbersome. Furthermore, all the components, particularly the viewing devices, are dedicated devices, which increases cost considerably.

[011] EXPLANATION OF THE INVENTION

[012] The apparatus of the invention overcomes these various difficulties and provides an effective method of breaking up lithiases by applying shock waves which are perfectly adapted in strength and precisely aimed, thereby eliminating the possibility of causing lesions in surrounding tissue. This is due specifically to the fact that the system for compensating wear on the electrodes proposed by the invention eliminates diagonal wear on the electrodes that causes the shock wave generator to become off-center relative to the emission focal point on the reflector. Furthermore, this device is easily manageable in comparison with known devices, making the procedure simple, quick, and efficient, since its aim is very precise. Moreover, the auxiliary equipment such as the viewing devices are not dedicated devices, and they can be used for other purposes.

[013] This goal is achieved by the lithotripter apparatus of the invention, characterized in that said means for compensating wear on the electrodes comprises at least one compensation mechanism for axially displacing the two electrodes independently of each other along an axis corresponding to the axis of symmetry of the reflector and to cause at least one of said electrodes to turn on its longitudinal axis. Because of this, the extremities of the electrodes wear regularly and can always be positioned precisely so that the shock wave generator which they constitute is centered on the emission focal point of the reflector forming the basin, whatever the extent of wear on the electrodes. As a result of this, one of the basic conditions set forth above, i.e., that the shock waves be properly aimed at the lithiases to be treated, is fulfilled.

[014] In a particularly advantageous manner, one of the electrodes is located along the axis of the reflector and housed inside a tube that is joined to a first mechanism which axially displaces the tube and the electrode it holds and rotates the tube on its longitudinal axis. The other electrode comprises two portions connected to each other with a small bar, one of said portions being located along the axis of the reflector and the other portion being housed inside a tube that is connected to a second mechanism which axially displaces the tube along with the electrode it holds.

[015] The apparatus preferably includes a computer for determining the respective spatial coordinates of the lithiasis to be treated and of the reflector, a means for emitting control signals as a function of the values determined for said spatial coordinates, and a means for displacing said reflector as a function of said signals so that the receptor focal point is positioned on the lithiasis. This method of operation provides a high degree of precision in positioning the lithiasis and offers unparalleled flexibility in use.

[016] Advantageously, the means for displacing said reflector comprises a housing supporting the basin which constitutes the reflector, a chariot to which the housing is attached, some generally horizontal, crossed slides allowing the chariot to be displaced in two orthogonal directions, some generally vertical slides allowing it to be displaced in a third direction, perpendicular to the two other directions, as well as a means for activating the chariot in these three directions. For this reason, it is only necessary to move the shock wave generator, and there is no need to move either the patient or the entire apparatus.

[017] According to a first advantageous embodiment, the live viewing device has a radioscopic device comprising an x-ray generator and an x-ray receptor means which are respectively attached to the two ends of an arc-shaped arm pivoting in a plane about its center, a radioscopic image display screen, and a means for communicating the visual data to the computer in order to determine the relative coordinates of the emission focal point and of the lithiasis.

[018] According to a second embodiment, said live viewing device comprises an echograph apparatus as well as at least two cameras which are offset from each other, an echograph image display screen, and a means for communicating the visual data to the computer in order to determine the relative coordinates of the emission focal point and of the lithiasis.

[019] In this instance, one of the cameras is advantageously located at the base of the apparatus, below the treatment zone, in order to furnish an image that is generally perpendicular to said zone, and the other camera is offset to the side in order to furnish an image that is oblique to said zone.

[020] SUMMARY DESCRIPTION OF THE DRAWINGS

[021] The present invention will be better understood with reference to the following description of a preferred embodiment of the lithotripter apparatus according to the invention and with reference to the drawings, provided by way of non-limiting examples, in which:

[022] Figure 1 shows a perspective view of the entire apparatus of the invention;

[023] Figure 2 is a schematic view showing the operating principles of the apparatus of the invention;

[024] Figure 3 is a schematic axial cross-section of the reflector and the electrodes of the lithotripter apparatus of the invention; and

[025] Figure 4 is a particular embodiment of the viewing device associated with the apparatus of the invention.

[026] METHOD(S) OF ACHIEVING THE INVENTION

[027] With reference to Figure 1, the lithotripter apparatus 10 as shown essentially comprises a frame 11 surmounted by a treatment table 12 which supports the patient to be treated. Frame 11 is in the form of a cabinet, with the right side 13 essentially containing the electrical and electronic equipment, the left side 14 essentially containing the mechanical equipment, and the center portion 15 principally containing a movable chariot 16 which holds a semi-ellipsoidal reflector 17 and a device which generates shock waves for dislocating the lithiases. A screen 18 held by an adjustable support 19 is attached to frame 11. A device for viewing of the treatment zone, one embodiment of which will be described with reference to Figure 4, is preferably independently associated with the device and with screen 18.

[028] Figure 2 is a schematic representation of reflector 17 surmounted by a membrane 31 and containing an acoustic transmitting liquid 32 which provides a continuous transmitting environment for the shock waves when the membrane is applied to the patient's body. The basin-shaped semi-ellipsoidal reflector 17 contains two electrodes 33 and 34, whose extremities 33a and 34a, located opposite each other, are positioned essentially axially relative to emission focal

point F_e of the ellipsoid. The formation of an electrical arc between the two electrodes following the discharge of a condenser in these electrodes provides a pressure wave that is reflected by the walls of the basin.

[029] As shown in the drawing, the shock waves generated by electrodes 33 and 34 are focused on a lithiasis 35 present in the patient's kidney and positioned so as to coincide with the receptor focal point F_r of the reflector. Electrodes 33 and 34 constitute a high yield electro-hydraulic pressure wave generator.

[030] Figure 3 is an axial cross-section of the basin which constitutes the semi-ellipsoidal reflector 17 and of the electrodes which constitute the electro-hydraulic pressure wave generator. The basin is attached to a housing 40 and contains the two electrodes 33 and 34 arranged so that the respective extremities 33a and 34a, which terminate in a point, are located on the axis of symmetry of said basin, on either side of emission focal point F_e of the reflector. Electrode 33 traverses an electrode-holder tube 41 made of plastic, located inside a fixed sleeve 42 that is axially attached to the bottom of the basin. The electrode-holder tube 41 is joined to a drive mechanism consisting of a reduction motor 43 that has a primary function of causing the axial displacement of electrode 33 to compensate for wear and to constantly replace its extremity 33a in its axial position near emission focal point F_e, and a secondary function of causing electrode 33 to rotate on its axis in order to avoid irregular diagonal wear that would have the adverse effect of causing extremity 33a to be off-center from emission focal point F_e.

[031] Electrode 34 consists of two parts 44 and 45 parallel to each other and joined by a small bar 46. Portion 45 is housed inside electrode-holder tube 47 which traverses the bottom of the basin inside a suitable sleeve 48. This electrode-holder tube 47 is connected to a drive mechanism comprising a reduction motor 49 which causes the axial displacement of electrode 34 to compensate for wear and which constantly returns its extremity 34a to its axial position near emission focal point F_e.

[032] Sleeve 42 contains a toric seal 50 that seals electrode-holder tube 41. Likewise, sleeve 48 contains a toric seal 51 that seals electrode-holder tube 47.

[033] Figure 4 shows a portion of the apparatus that constitutes the means for live viewing 60 of the treatment zone. This device is preferably independent from the apparatus, but it can also be permanently attached to it. In the example shown, it consists of an arc-shaped radioscopic arm 61, called a C arm, holding an x-ray generator 62 on its lower extremity and an x-ray receiver means on its upper extremity, such as a light amplifier 63. The C arm is circular and it pivots in its plane about its pivot center R which is offset from axis 64 defined by generator 62 and amplifier 63. The offset d existing between R and the point of intersection O of axis 64 with the perpendicular axis passing through the pivot center R is of the order of 40-80 mm.

[034] In another embodiment, this x-ray viewing device can be replaced by an echograph lithiasis locator device which comprises, in a manner known in the art, an echograph sensor and a screen 18 which displays the capture images.

[035] During the procedure, two successive views are taken. One view is taken perpendicular to table 12 which supports the patient, and the other is taken obliquely to the table. The coordinates that are located and displayed on the screen are processed by a computer which precisely determines the coordinates of the shock wave generator. This procedure constitutes a calibration of the apparatus by means of triangulation. It is made possible by the fact that the C arm can pivot in its plane about its pivot center, which is located at the geometric center of the circular arc. After placing the patient on the operating table, the same procedure is followed to determine the position of the lithiasis. A first radioscope of the treatment zone is performed with the radioscopic arm in vertical position and a second radioscope of this zone is performed with the arm in oblique position, the angle being, for example, of the order of 20 degrees relative to the vertical. The coordinates of the lithiasis in the two images are introduced into the computer. It accurately determined the position of the shock wave generator so that emission focal point F_e can be positioned in such a way that receptor focal point F_r, corresponds to the lithiasis.

[036] A similar procedure can be performed by replacing the radiograph with an echograph. In this embodiment the apparatus comprises two respective cameras,

called indexing cameras, one of which is located at the base of the apparatus below the treatment area, in order to furnish an image that is essentially perpendicular to this zone, and the other of which is offset to the side in order to furnish an image that is oblique in relation to said zone. When the operator performs an echogram on a patient using an echographic sensor, the indexing cameras register the position of the sensor with in the area of the apparatus. A computer determines the spatial coordinates of this position so that the position of the lithiasis can then be determined and the precise position of the shock wave generator can be defined allowing emission focal point F_e to be positioned in such a way that receptor focal point F_r corresponds to the lithiasis.

[037] After determining the coordinates, emission focal point F_e is placed in the proper position. For this purpose the apparatus has means for displacing reflector 17, or more specifically housing 40 that supports the basin forming the reflector, to the desired position. This means consists of a chariot to which said housing is attached, essentially horizontal, crossed slides for displacing the chariot in two orthogonal directions, essentially vertical slides for displacing it in a third direction perpendicular to the two other directions, as well as a means for activating the chariot in these three directions. The means is controlled by signals generated by the computer or by a signal generator associated with the computer and preferably transmitted to stepping motors connected to mechanical devices which displace the chariot.

Claims

1. A lithotripter apparatus comprising a frame (11), a treatment table (12) for supporting a patient during the process of fragmenting the lithiasis (35), a device for generating shock waves by means of an electrical arc, a means for focusing these shock waves on said lithiasis, and a device (60) for live viewing of the treatment zone, said device for generating shock waves comprising two electrodes (33, 34) separated from each other and connected to a high voltage energy generating circuit, and the means for focusing these shock waves comprising a semi-ellipsoidal reflector (17), the extremities (33a, 34a) of said electrodes being located essentially at one (F_e) of the focal points of the reflector (17), the other focal point (F_r) of the reflector being centered on said lithiasis, said electrodes being equipped with a means of wear compensation, characterized in that said means for wear compensation on the electrodes (33, 34) comprises at least one compensation mechanism which axially displaces the two electrodes, independently of each other, along an axis corresponding to the axis of symmetry of the reflector (17) and turns at least one of said electrodes on its longitudinal axis.

2. An apparatus according to claim 1 characterized in that one (33) of the electrodes is located along the axis of the reflector (17) and housed inside a tube (41) which is joined to a first mechanism designed to axially displace said tube along with the electrode it contains and to cause said tube to rotate along its longitudinal axis.

3. An apparatus according to claim 1 characterized in that the other electrode (34) comprises two portions (44, 45) connected to each other by a small bar (46), one (44) of said portions being located along the axis of the reflector (17) and the other portion (45) being housed inside a tube (47) which is connected to a second mechanism designed to axially displace said tube along with the electrode it contains.

4. An apparatus according to claim 1, characterized in that it comprises a computer designed to determine the spatial coordinates of the lithiasis to be treated (35) and of the reflector (17), a means for emitting control signals as a

function of the values determined for said spatial coordinates, and a means for displacing said reflector as a function of said signals so as to position the receptor focal point (F_r) on said lithiasis.

5. An apparatus according to claim 4 characterized in that the means for displacing the reflector (17) comprises a housing (40) that holds the basin constituting the reflector, a chariot to which the housing is attached, slides that are essentially horizontal and crossed allowing the chariot to be displaced in two orthogonal directions, slides that are essentially vertical allowing it to be displaced in a third direction perpendicular to the two other directions, as well as devices activating the chariot in these three directions.

6. An apparatus according to claim 1 characterized in that the live viewing means (60) includes a radioscopic apparatus comprising an x-ray generator (62) and an x-ray receiver (63), respectively attached to the two extremities of an arc-shaped arm (61) pivoting in its plane about its center, a scree (18) for displaying the radioscopic images, and a means for communicating the visual data to a computer in order to determine the relative coordinates of the emitting focal point (F_e) and of the lithiasis.

7. An apparatus according to claim 1 characterized in that the live viewing device (60) comprises an echograph device as well as at least two cameras which are offset from each other, a screen for displaying the echograph images and a means for communicating the visual data to said computer in order to determine the relative coordinates of the emitting focal point (F_e) and of the lithiasis.

8. An apparatus according to claim 7 characterized in that one of the cameras is located at the base of the apparatus, below the treatment zone, in order to furnish an image essentially perpendicular to said zone, and the other camera is offset to the side in order to furnish an image oblique to said zone.

ABSTRACT OF THE DISCLOSURE

The invention concerns a lithotripter apparatus for very accurately breaking up kidney stones using a shock wave generator while compensating the wear of the electrodes constituting said generator. It comprises a mount frame (11), a treatment table (12) to bear a patient during a lithiasis (35) break up treatment, a shock wave generator, mechanisms for focusing the shock waves onto the lithiasis and a device for displaying live (60) the treatment zone, the shock wave generator comprising two electrodes (33, 34) spaced apart from each other. The mechanisms focusing the shock waves comprise a semi-ellipsoidal reflector (17), the ends (33a, 34a) of the electrodes being arranged substantially at one (F_e) of the focal points of the reflectors(17), the other focal point (F_r) of the reflector being centered on the lithiasis. The electrodes (33, 34) are provided with a wear-compensating mechanism designed to move them axially, independently of each other, along an axis corresponding to the axis of symmetry of the reflector (17), one of the electrodes being further capable of rotating relative to the second one such that the wear is uniform.

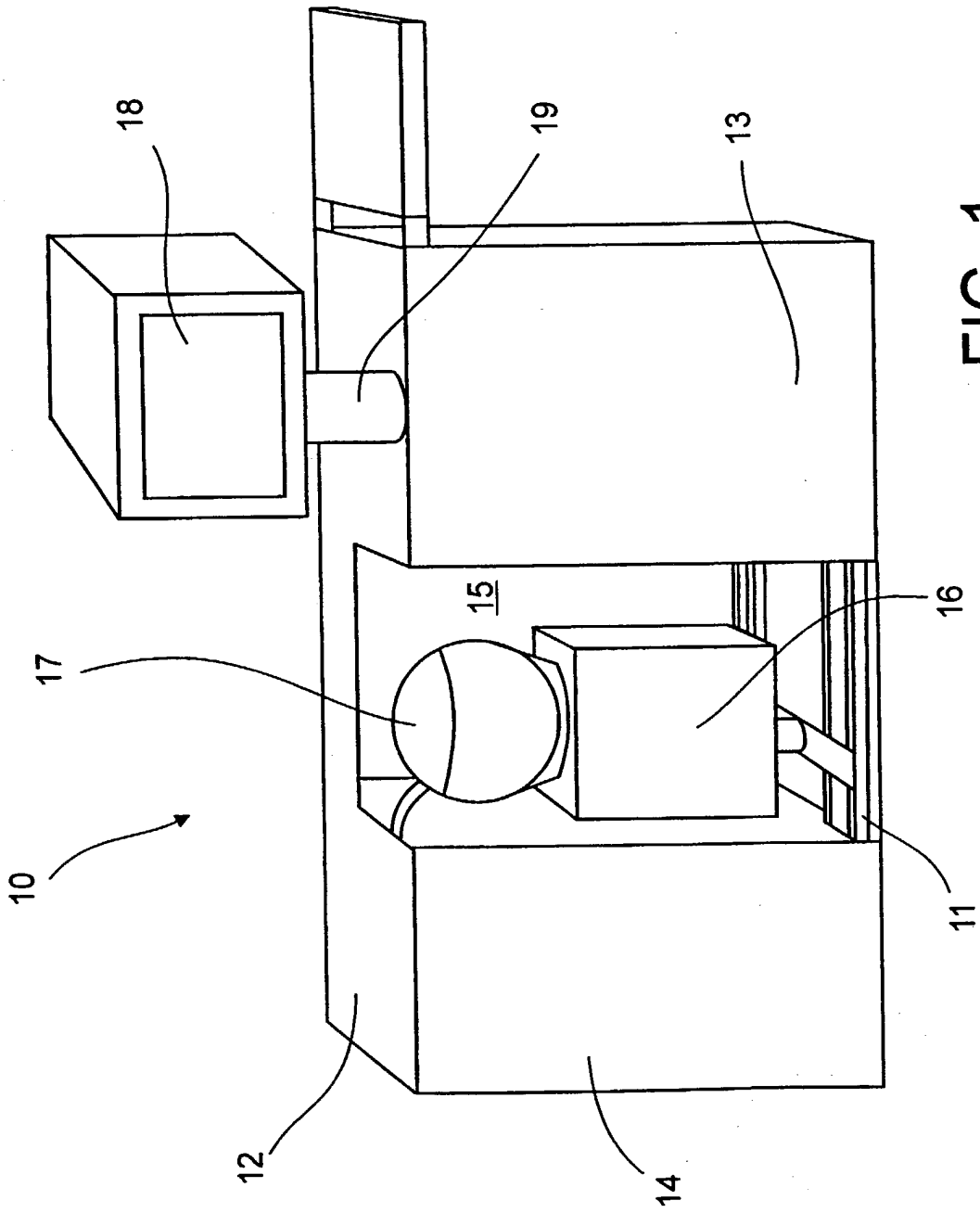

FIG. 1

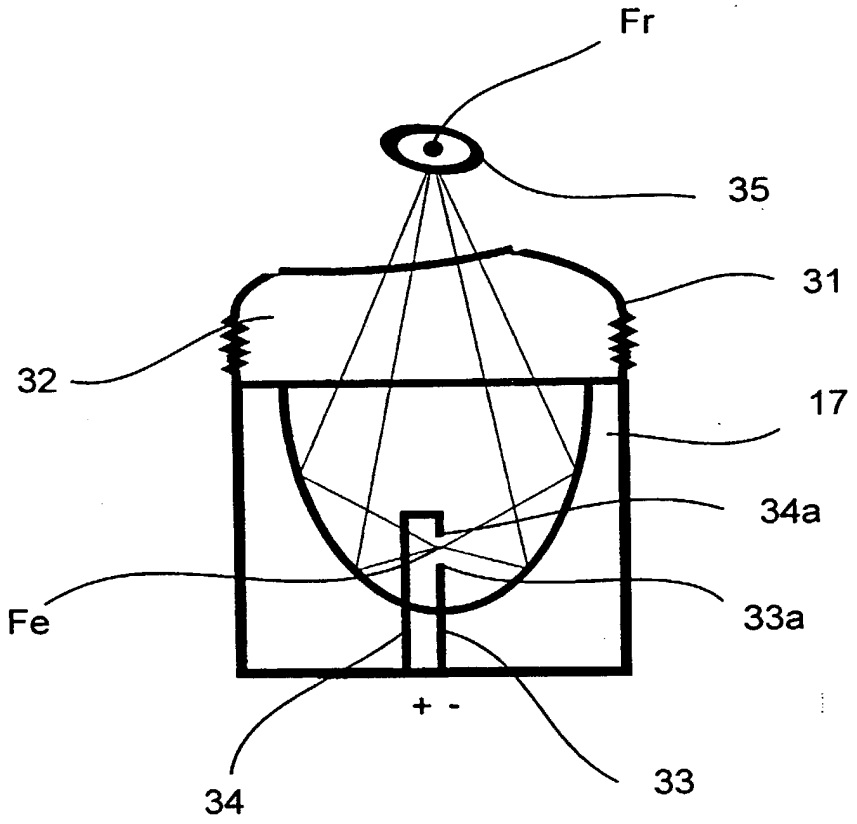

FIG. 2

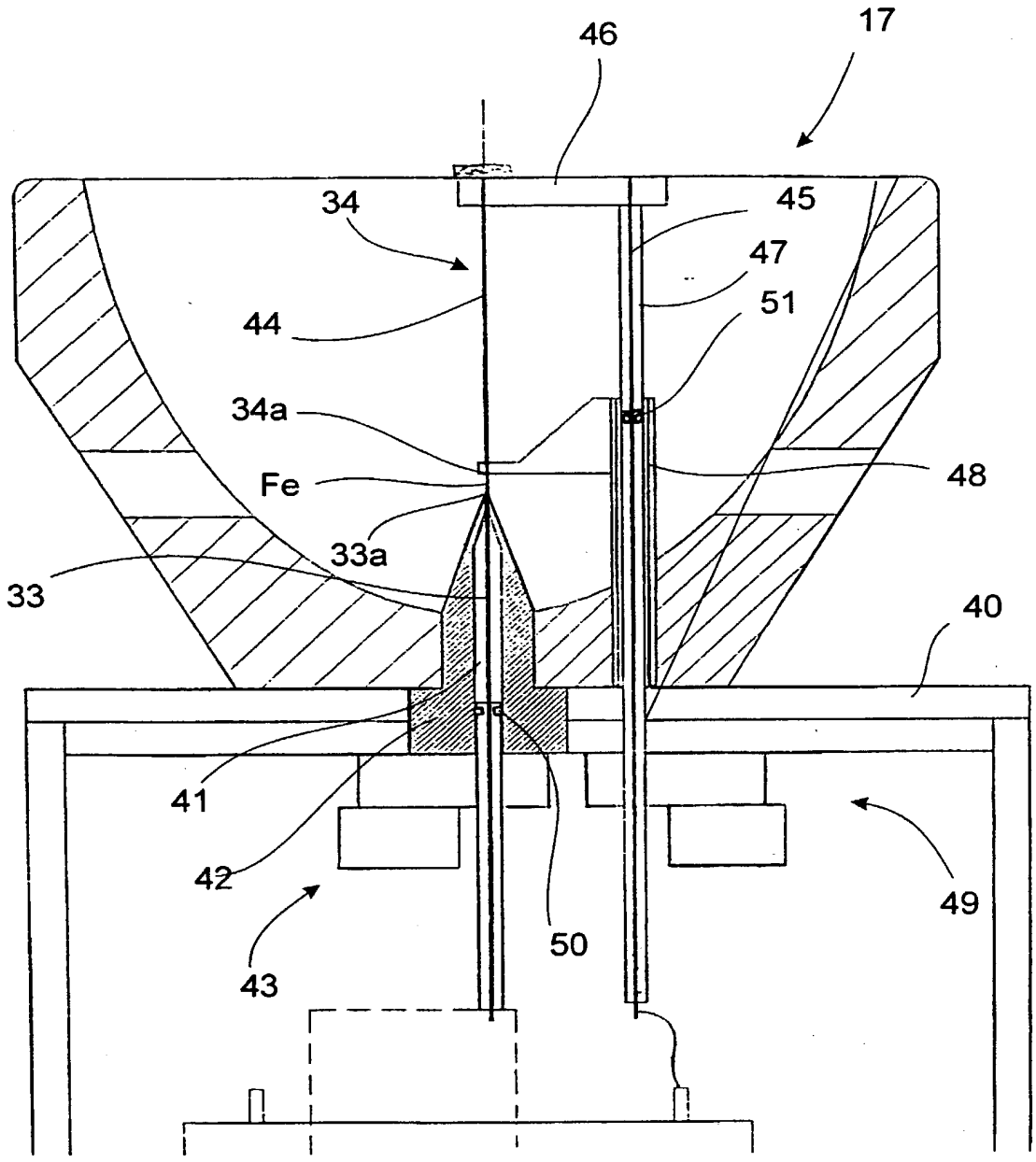

FIG. 3

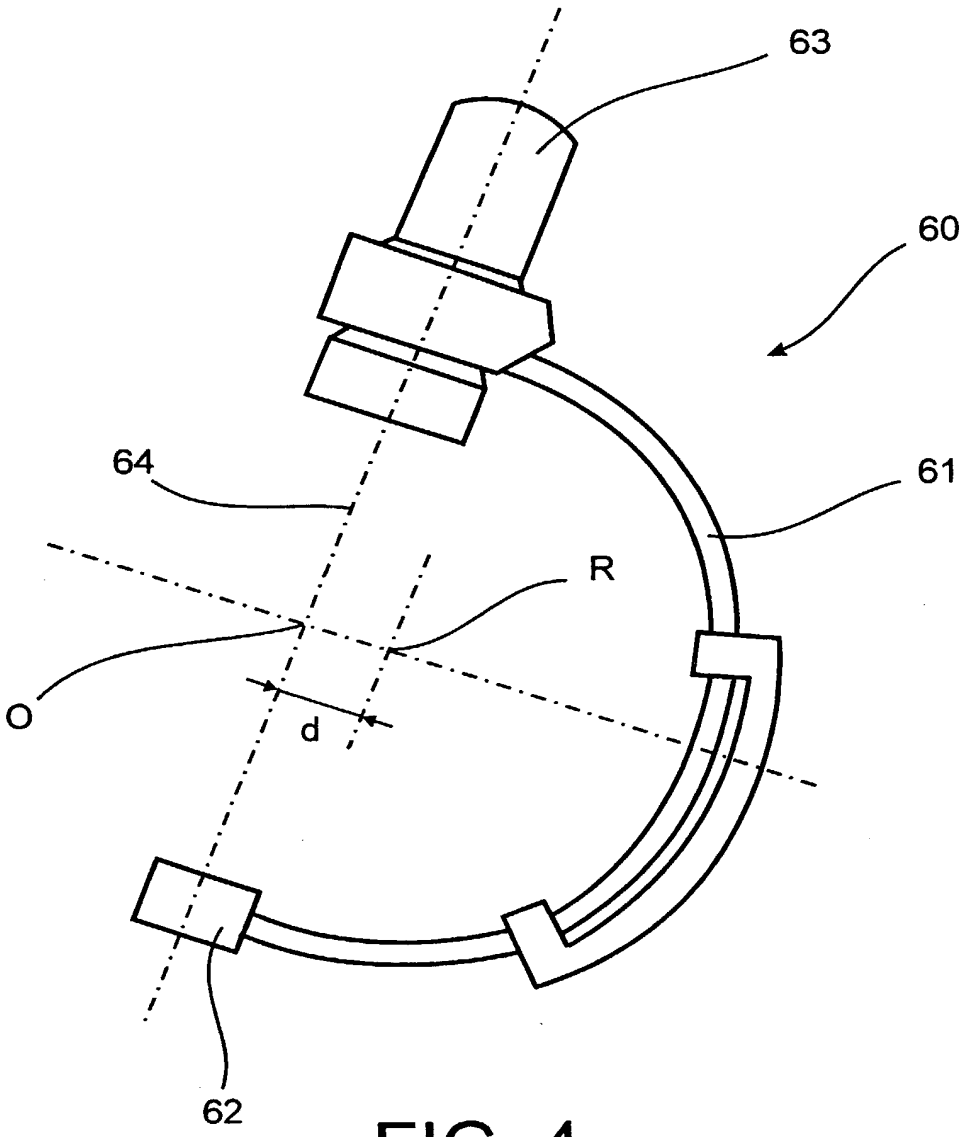

FIG. 4

NITROS P158US

COMBINED DECLARATION AND POWER OF ATTORNEY

(Original, Design, National Stage of PCT, Supplemental)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: (check one applicable item below)

- ☐ original
- ☐ design
- ☐ supplemental
- ■ National Stage of PCT
- ☐ divisional (see added page)
- ☐ continuation (see added page)
- ☐ continuation-in-part (see added page)

INVENTORSHIP IDENTIFICATION

My/our residence, post office address and citizenship is/are as stated below next to my/our name. I/We believe that the named inventor or inventors listed below is/are the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

LITHOTRIPTER APPARATUS

SPECIFICATION IDENTIFICATION

The specification of which: (complete (a), (b) or (c))

(a) ☐ is attached hereto.

(b) ☐ was filed on _____ as
☐ Serial No. _____ or
☐ Express Mail No. _____ as Serial No. (not yet known) and was amended on _____(if applicable).

(c) ■ was described and claimed in PCT International Application No. PCT/IB00/01400 filed on October 2, 2000 and as amended under PCT Article 19 on _____ (if any).

(d) ☐ amended on _____

POWER OF ATTORNEY

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (list name(s) and registration number(s))

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☐ Attached as part of this Declaration and Power of Attorney is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

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ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I/We hereby state that I/we have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I/We acknowledge the duty to disclose to the United States Patent Office all information which is known to be material to patentability of this application as defined in § 1.56 of Title 37 of the Code of Federal Regulations.

PRIORITY CLAIM

I/We hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me/us on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

COUNTRY	APPLICATION NO.	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119
FRANCE	99 12431	01 October 1999	☒YES ☐NO
			☐YES ☐NO
			☐YES ☐NO
			☐YES ☐NO
			☐YES ☐NO

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

☐ I/We hereby claim the benefit, under 35 U.S.C. 119(e), of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YY)	☐ Additional provisional application numbers are listed on a supple-mental priority data sheet PTO/SB/02B attached hereto.

DECLARATION

I/We hereby declare that all statements made herein of my/our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of ~~sole or first joint~~ inventor: SANGOUARD Patrick

Inventor's signature: _____ Date: 27 Juin 2002

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Post Office Address: Same as above Country of Citizenship: France

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FRX

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By virtue of this regulation, each inventor executing the Declaration for the filing of a patent application acknowledges his/her duty to disclose information of which he/she is aware and which may be material to the examination of the application.

Inherent in this is the duty to disclose any knowledge or belief that the invention:

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(b) was patented or described in any printed publication in any country before his/her invention thereof or more than one year prior to the actual filing date of the United States patent application;

(c) was in public use or on sale in the United States more than one (1) year prior to the actual filing date of the United States patent application; or

(d) has been patented or made the subject of inventor's certificate issued before the actual filing date of the United States patent application in any country foreign to the United States on an application filed by him/her or his/her legal representative(s) or assign(s) more than twelve (12) months before the actual filing date in the United States.

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